Group V, claims 13 to 15, drawn to a kit, classified in class 424, subclass 85.1; and

Group VI, claim 16, drawn to a composition comprising erythropoietin and interferon, classified in class 530, subclass 350.

Applicant provisionally elects with traverse for further prosecution in the present application the invention identified in the Office Action as Group III, claims 2 and 3. Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

The Office Action contends that restriction is proper under 35 U.S.C. § 121 since the inventive Groups are directed to different methods which appear to constitute patentably distinct inventions for several reasons. Specifically, the Examiner asserts that Groups I-IV are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. The Examiner further asserts that the Groups are drawn to treating different patient populations. The Office Action also contends that the invention of Group V is unrelated to the inventions of Groups I-IV since the claims of Groups I-IV do not require the packaged kit of Group V. In addition, the Office Actions purports that product of Group VI can be used in a different process other than the methods of Groups I-IV, the invention of Group VI is distinct. It is respectfully requested that the restriction requirement be reconsidered and withdrawn and that there be search, examination and prosecution of all of the claimed subject matter, namely the claims of Groups I-VI designated in the Office Action of the present application for the reasons provided as follows.

Under 35 U.S.C. § 121, "two or more independent and distinct inventions ... in one application may... be restricted to one of the inventions." Inventions are "independent" if

there is no distinct relationship between two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER" (MPEP 802.01, August, 2001) (emphasis is original). However, even with patentably distinct inventions, restriction is not proper unless "the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following" (MPEP 808.02):

1. Separate classification thereof;

2. Separate status in the art when they are classifiable together; or

3. Different field of search.

Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803) (emphasis added).

The Groups designated by the Examiner fail to define methods and compositions warranting separate examination and search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application.

The elected invention provides for a method for treating ribavirin or ribavirin and interferon-alpha induced anemia comprising administering erythropoietin to a patient in need thereof. Claim 2 further adds the recitation that the erythropoietin can be administered as a liquid preparation, subcutaneously, parenterally, intradermally, intramuscularly or intravenously. Similarly, claim 3 specifies the erythropoietin as a suspension, emulsion, syrup or elixir. A single inventive concept however links all of the claims of Groups I-VI: the new use of

erythropoietin to treat an anemia condition caused by the treatment of a viral infection such as a hepatitis C with ribavirin or the combination of ribavirin and interferon-alpha. Although the administration of ribavirin and the coadministration of ribavirin and interferon-alpha is a standard treatment for viral infections such as hepatitis C, anemia is a major side effect of treatment and represents a serious health problem for which the present invention provides a solution. Accordingly the claims of the present application represent a continuous web of knowledge and are unified under a single inventive context. Thus, there is no undue or serious burden in searching and examining all of the claims of Groups I-VI in the present application.

In more detail, the Office Action contends that Groups I-IV are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Specifically, the Examiner asserts that the invention of Group I relates to the treatment of hepatitis C by administering a DNA vector that expresses erythropoietin *in vivo*, which is a structurally and functionally distinct element from the other groups. Applicant respectfully disagrees. Since providing a vector that administers erythropoietin *in vivo* is a way to administer erythropoietin to a patient in need thereof, the claims of Group I are related to the claims of Groups II-IV, which also specify the administration of erythropoietin to a patient in need thereof, further evidencing that there is no undue or serious burden in searching and examining the claims of Groups I-IV in the present application.

Further, the Examiner asserts that the claims of Group II require the treatment of hepatitis C by administering ribavirin and interferon-alpha which is a distinct element from the other groups and achieves a different goal. Applicant respectfully disagrees. The invention of Groups III and IV, which relate to methods for treating ribavirin or ribavirin and interferon-alpha induced anemia by administering erythropoietin, are indeed related and inextricably linked to the

invention of Groups I and II, which relate to methods for treating hepatitis C by administering ribavirin or ribavirin and interferon-alpha in combination with erythropoietin, since the administering of ribavirin or ribavirin and interferon-alpha in combination with erythropoietin to treat hepatitis C can induce anemia as specified in the inventions of Groups III and IV. In other words, treating the anemia by administering erythropoietin according to the inventions of Groups III and IV is related to an improvement to the methods of treating hepatitis C with ribavirin or ribavirin and interferon-alpha by administering erythropoietin according to the inventions of Groups I and II. Thus, the subject matter of the claims of Groups I-IV significantly overlaps. Accordingly, there is no undue or serious burden in searching and examining all of the claims of Groups I-VI in the present application. Therefore, the prerequisite for restriction is not met.

The Examiner further contends that the inventions of Groups V and I-IV are unrelated since they are not disclosed as capable of use together and they have different modes of operation, different function, or different effects. Applicant respectfully disagrees. Claim 13 relates to a kit comprising ribavirin and erythropoietin, or ribavirin, erythropoietin and interferon-alpha for a least one administration of ribavirin and erythropoietin or ribavirin, erythropoietin and interferon-alpha. Claims 14 limits the kit to contain only erythropoietin and interferon-alpha. Claim 15 specifies that the erythropoietin and interferon-alpha are in a form capable of being admixed prior to administration. Applicant respectfully points out that the kit of the Group V invention could be used to achieve the goals of any of the inventions of Groups I-IV, since the claims of Groups I-IV relate to the administration of erythropoietin in combination with interferon-alpha. Accordingly, there should be no undue or serious burden in searching and examining the claims of Groups I-V in the present application.

The Office Action also contends that the invention of Group VI is distinct from the inventions of Groups I-IV because the product (i.e., composition comprising erythropoietin and interferon-alpha admixed together) of Group VI can be used in the methods of Groups I-IV, but also in a different process of using such as making antibodies. Applicant suggests that since the composition of claim 16 could be used in any of claims of Groups I-IV, the claims of Groups I-VI may be searched and examined together without serious burden, as they all relate to erythropoietin and its administration to treat hepatitis C in conjunction with the administering of ribavirin or ribavirin and interferon-alpha or anemia resulting from the administration of ribavirin or ribavirin and interferon-alpha.

Further and by the Examiner's own classification scheme, the claims of Groups I-IV inventions are all classified in class 514 and moreover, Group II-IV claims are classified in subclass 2. Thus, given the Examiner's classification of the claims of Groups I-IV into the identical class (514), and that Groups II-IV are further classified into subclass 2, there should be no burden upon searching all of the claims in a single search. The present claims represent a web of knowledge and continuity of effort that merits examination in a single application.

Thus, the criteria necessary for classifying Groups I-VI as distinct inventions has not necessarily been met. Accordingly, the subject matter of the claims can be used together, and searched together since all six Groups relate to compositions and methods of using erythropoietin in the treatment of hepatitis C in conjunction with the administering of ribavirin or ribavirin and interferon-alpha or an anemia condition induced by treatment of hepatitis C with ribavirin or ribavirin and interferon-alpha.

It is respectfully submitted that examination of all of the claims pending in this application is in the spirit of the right of rejoinder such that the restriction requirement should be reconsidered, and reformulated or withdrawn entirely.

It would seem, that to require the filing of five additional divisional applications directed to the claims of Groups I, II, IV, V and VI will result in the very same search being repeated, but at a later date. It is submitted that these duplicate searches would be quite inefficient to the operation of the Patent and Trademark Office. Furthermore, it is likely that the same Examiner would be in charge of the divisional cases; but since those divisional applications will be examined at a much later date, the Examiner will have to conduct duplicate, redundant searches at the time she examines the divisional applications. Alternatively, if a different Examiner were assigned to the divisional applications, a significant loss of PTO efficiency would be incurred as a result of the examination of the divisional cases.

Thus, the only logical outcome of the present restriction requirement would be to delay the examination of the claims of Groups I, II, IV, V and VI, resulting in inefficiencies and unnecessary expenditures by Applicant and the PTO, and since a single search can be performed for all of Group I-VI claims without any significant burden on the Office, it is respectfully requested that this restriction requirement be withdrawn.

In this regard the Examiner is respectfully invited to consider the extreme prejudice to Applicant by the present restriction requirement, including: the necessity of having to pay five additional filing fees to the USPTO and others for prosecuting five additional applications; and, the loss of patent term for Groups I, II, IV, V and VI claims if Applicant must now file separate applications at this time directed thereto due to prosecution of such applications beginning far later than prosecution to date in the present application, and to the post-GATT 20

year from earliest U.S. filing date patent term and also in view of the enactment of the American Inventors Protective Act.

Additionally, the Examiner is respectfully invited to review the text of MPEP 803, which in part states (with emphasis) that:

> If the search and examination of an entire application can be **made without serious burden, the examiner must examine it on the merits**, even though it includes claims to distinct or independent inventions.

The results of the present restriction requirement are inefficiencies and unnecessary expenditures by both the Applicant and the USPTO, and extreme prejudice to Applicant; and, restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action, there are relationships among the six species of Group I-VI claims, all of which militate against restriction.

Hence, it is evident that there is unity of invention and allowable subject matter in the pending claims. In view of the foregoing, reconsideration and withdrawal of the requirement for restriction and favorable consideration of all of the claims on the merits are respectfully requested.

Thus, if the restriction requirement is nonetheless maintained, Applicant reserves the right of rejoinder, as mandated by the MPEP.

Early and favorable examination of all of the claims on the merits is respectfully requested.

In view of the foregoing, reconsideration and withdrawal of the requirement for restriction and favorable reconsideration of Groups I-VI claims on the merits are respectfully requested.

Applicant believes that there are no fees required for the filing of this paper; however, the Commissioner is hereby authorized to charge any fees occasioned by this paper or credit any overpayment to Deposit Account No. 50-0320.

Respectfully submitted,

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